



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/847,601

05/01/2001

Alfred S. Lewin

36689.140

7183

27683 7590 03/14/2008

HAYNES AND BOONE, LLP

901 Main Street

Suite 3100

Dallas, TX 75202

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

03/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/847,601	LEWIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kimberly Chong	1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 14-42, 58-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

### ***Status of Application/Amendment/Claims***

Applicant's response filed 10/31/2007 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 06/13/2007 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 10/31/2007, claims 1-59 are pending in the application. Claims 1, 4, 14-42 and 58-59 are currently under examination and claims 2-3, 5-13 and 43-57 are withdrawn as being drawn to a non-elected invention. Claims 4 and 58 are free of the prior art of record and searched.

***Response to Applicant's Arguments***

***Re: Claim Objections***

The objection of claims 1 and 4 as being objected to as reciting non-elected subject matter is withdrawn in response to claim amendments filed 10/31/2007.

The objection of claim 4 as being objected to as being dependent upon a withdrawn base claim and reciting non-elected subject matter is withdrawn in response to claim amendments filed 10/31/2007.

***Re: Claim Rejections - 35 USC § 103***

The rejection of claims 1, 8, 14-42 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wraight et al. (of record), Thompson et al. (of record), Pavco et al. (of record) and Kido et al. (of record) is maintained for the reasons of record filed in the Office action mailed 06/13/2007.

Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive. Applicant argues none of the cited references alone or in combination provides any guidance about selecting the particular target sequence having SEQ ID NO. 88 and further argues none of the cited references provide any expectation of success in constructing a ribozyme that comprises the sequence set for as SEQ ID No. 100. As such, Applicant argues the references cannot render the claimed invention obvious because there is insufficient teaching, motivation, suggestion or expectation of

success at using the nucleotides sequence (SEQ ID No. 88) within the IGF-1 receptor specific mRNA to produce a ribozyme that comprises SEQ ID No. 100.

At the outset, the instant claims are not limited to the ribozyme sequence having SEQ ID No. 100. The claims as amended recite the ribozyme of claim 1 *or* claim 4 and the ribozyme recited in claim 1 is not limited to a ribozyme consisting of or comprising any particular sequence. As such, the references do not need to teach a ribozyme comprising SEQ ID No. 100.

Applicant's argument that there is insufficient teaching, motivation, suggestion or expectation of success at using the nucleotides sequence (SEQ ID No. 88) within the IGF-1 receptor specific mRNA to produce a ribozyme is not convincing. Wraight et al. specifically teach targeting the IGF-1 mRNA that comprises SEQ ID No. 88, as instantly claimed, using an antisense compound for the purpose of inhibiting expression from said gene. The claims as recited are not limited to a ribozyme specifically targeting a region of SEQ ID No. 88, the ribozyme only need to be capable of specifically cleaving a sequence *that comprises* SEQ ID No. 88, therefore, the ribozyme can bind and cleavage on any part of the sequence. Given that Thompson et al. teach how to make and use ribozyme molecules to target any gene and teach the enzymatic nature of ribozymes is advantageous over technologies such as antisense technologies, one of skill in the art would have been motivated to substitute a ribozyme instead of an antisense compound to target an IGF-1 gene. Moreover, one of skill in the art would have been further motivated to target the specific region of SEQ ID No. 88 taught by

Art Unit: 1635

Wraight et al. given Wraight et al. teach efficient gene inhibition using an antisense compound targeted to said specific region.

Furthermore, one would have had a reasonable expectation of success at making a ribozyme targeted to IGF-I given that the IGF-I sequence was known, as evidenced by Wraight et al. making specific inhibitory sequences targeted to IGF-I, and further given that Thompson et al. provides a detailed disclosure of how to make any ribozyme targeted to any sequence.

Thus, the rejection of record is maintained.

### ***Response to Applicant's Request for Rejoinder***

Applicant's request for rejoinder will not be considered because the subject matter of elected Group I has not been found allowable.

### ***Request for Interview***

Applicants have requested an interview and state they have submitted a 90-day deferral request along with the RCE. This request has not been forwarded to Examiner and has not been made of record. Applicant's representative is encouraged to call Examiner at the contact information provided below to request an interview.

### ***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the

Art Unit: 1635

grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

Art Unit: 1635

been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

KC

Examiner Art Unit 1635

/Sean R McGarry/

Primary Examiner, Art Unit 1635